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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,908	12/18/2006	Amar Lulla	PAC/23361 US (4137-00700)	9899

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EXAMINER	
PURDY, KYLE A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,908	LULLA ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/24/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 09/24/2008 wherein claim 1 has been amended.

2. Claims 1-17 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 09/24/2008 regarding the rejection of claims 1-4, 6-9 and 11-17 made by the Examiner under 35 USC 102(b) over Wain (WO00/45795) have been fully considered but they are not found persuasive.

4. Applicants arguments filed 09/24/2008 regarding the rejection of claims 1-4, 6-9 and 11-17 made by the examiner under 35 USC 102(b) is **MAINTAINED** for the reasons of record in the office action mailed on 04/15/2008.

5. In regards to the 102(b) rejection, Applicant asserts the following:

A) Wain does not teach a composition which comprises both 0.1 to about 5.0% by weight of a VP-VA copolymer AND at least 60% by weight of non-aqueous solvent.

6. With respect to assertion A, this argument is perplexing. Applicant is directed to Example 12, as was noted in the office action mailed on 04/15/2008 which discloses a composition comprising 4% by weight VP/VA copolymer, permeation enhancers in an amount of 5% by weight and a non-aqueous solvent in an amount of 83% by weight. Thus, the disclosure of Wain still anticipates the instant claims despite Applicants amendment.

7. Applicants arguments filed 09/24/2008 regarding the rejection of claims 1-17 made by the Examiner under 35 USC 103(a) over Wain in view of Foldvari (Chem. Engineering, 2000) have been fully considered but they are not found persuasive.

8. Applicants arguments filed 09/24/2008 regarding the rejection of claims 1-17 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 04/15/2008.

9. In regards to the 103(a) rejection, Applicant asserts the following:

A') The Office Action does not clearly articulate nor explicitly support its obviousness rejection under 103(a).

10. With respect to assertion A', this argument is confounding because in the office action mailed on 04/15/2008, the Examiner provided sufficient motivation to combine the teachings of Wain and Foldvari. It was pointed out that Wain, while it did teach some enhancer, failed to teach a composition comprising permeation enhancers selected from menthol, myristyl lactate and so on. Foldvari was applied to show that these compounds are commonly used for such purposes, and that it would have been obvious to substitute one for the other. And because Wain motivates using enhancers in the composition, anyone of ordinary skill in the art would be capable of scouring the art in search of one, so long as it fulfills the purpose set forth by Wain. This is instantly the case. Therefore, Applicants arguments are not found persuasive.

Maintained Rejections

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1-4, 6-9 and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wain et al. (WO00/45795; of record, see IDS), evidenced by STN search results.**

13. Wain et al. ('Wain) is drawn to a topical medicinal spray composition which comprises one or medicaments in a non-aqueous vehicle and one or more film forming polymers (see abstract). Example 12 discloses a sample spray formulation which comprises the pharmaceutically active agent estradiol at a concentration of 1 % w/w (see instant claims 1 and 15-17), the film forming polymers PVP-VA (i.e. polyvinylpyrrolidone-vinyl acetate copolymer, VP/VA, see STN search results) at a concentration of 4 % w/w (see instant claims 1-4), the anti-nucleating agent PVP K-30 (polyvinylpyrrolidone, see STN search results) at a concentration of 6 % w/w (see instant claims 6-8) and the non-aqueous solvents acetone, methylene chloride and ethanol which are contained at concentrations of 27 %m 28 % and 28% w/w, respectively (see instant claims 1 and 13-14). The sum of the non-aqueous solvents results in a non-aqueous vehicle which comprises at least about 60 % by weight of the formulation (see instant claim 12). The composition of Example 12 also comprises polyethylene glycol 6000 and polyethylene glycol at a concentration of 2 % and 3 % w/w/, respectively for a total of 5%. It is taught in the specification of Wain that polyethylene glycols are polyhydric alcohols, which in turn are skin permeation enhancers (see page 7, 5th paragraph and page 8, 3rd paragraph; see instant claims 9 and 11).

14. Thus, the limitations of the instantly rejected claims are met entirely by Wain.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wain et al. (WO 00/45795; of record, see IDS) in view of Foldvari (PSTT, 2000, 3(12), 417-425).**

17. Wain et al. ('Wain) is drawn to a topical medicinal spray composition which comprises one or medicaments in a non-aqueous vehicle and one or more film forming polmers (see abstract). Example 12 discloses a sample spray formulation which comprises the pharmaceutically active agent estradiol at a concentration of 1 % w/w (see instant claims 1 and 15-17), the film forming polymers PVP-VA (i.e. polyvinylpyrrolidone-vinyl acetate copolymer, VP/VA, see STN search results) at a concentration of 4 % w/w (see instant claims 1-4) and the anti-nucleating agent PVP K-30 (polyvinylpyrrolidone, see STN search results) at a concentration of 6 % w/w (see instant claims 6-8). It is noted that Wain states that the film forming polymer can be contained in the composition from 0.1% to 10% w/w (see claim 5; see instant claim 5). The composition of Example 12 also contains the non-aqueous solvents acetone, methylene chloride and ethanol which are contained at concentrations of 27 %, 28 % and 28% w/w, respectively (see instant claims 1 and 13-14). The sum of the non-aqueous solvents results in a non-aqueous vehicle which comprises at least about 60 % by weight of the formulation (see instant claim 12). The composition of Example 12 further comprises polyethylene glycol (PEG) 6000 and polyethylene glycol at a concentration of 2 % and 3 % w/w, respectively for a total of 5

%. It is taught in the specification of Wain that polyethylene glycols are polyhydric alcohols, which in turn are skin permeation enhancers (see page 7, 5th paragraph and page 8, 3rd paragraph; see instant claims 9 and 11).

18. Wain fails to teach transdermal permeation enhancers as being selected from menthol, dimethylisosorbide, glycerylmonooleate and myristyl lactate.

19. Foldvari is a review article drawn to non-invasive administration of drugs through the skin. It is taught that menthol (terpene) is a useful penetration enhancer which acts by disrupting intercellular lipid orders (see instant claim 10). Moreover, addition of menthol to skin increases net electrical conductivity which indicates the opening of polar pathways in the stratum corneum and allows for simplifying the passage of active agents (see Table 1, page 420).

20. Thus, one ordinarily skilled in the art, at the invention was made would be motivated to combine the teachings of Wain and Foldvari with a reasonable expectation for success in arriving at a transdermal spray formulation comprising a pharmaceutically active agent, a VP-VA copolymer, a non-aqueous vehicle, a penetration enhancer, and a anti-nucleating agent at the required weight percentages. Wain teaches a composition which comprises an active agent (estradiol), an anti-nucleating agent (PVP-k 30), a film forming polymer (PVP-VA), penetration enhancer (PEG) and non-aqueous solvents acetone (acetone, ethanol and methylene chloride). Although Wain includes penetration enhancers in their composition, Wain fails to specifically disclose using menthol as such. Foldvari et al. is a review article drawn to penetration enhancers and their use to improve transdermal delivery of pharmacologically active agents. It is specifically taught that menthol is useful as a penetration enhancer. As Wain motivates using a penetration enhancer in the composition, it follows that employing any penetration enhancer

would be useful so long as it fulfills the role of performing its function. If one arrived at menthol out of the many potential enhancers and the product was successful, such a result would not be due to innovation but rather due to ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
November 18, 2008

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611